A I D S TREATMENT N E W S

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Contents

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Statement of Purpose:
AIDS Treatment News reports on experimental and standard treatments, especially those available now. We interview physicians, scientists, other health professionals, and persons with AIDS or HIV; we also collect information from meetings and conferences, medical journals, and computer databases. Long-term survivors have usually tried many different treatments, and found combinations that work for them. *AIDS Treatment News* does not recommend particular therapies, but seeks to increase the options available.

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Bush Signs Global AIDS Bill

On May 27 President Bush signed legislation passed by both houses of Congress authorizing up to $15 billion in funding over the next five years for global AIDS, tuberculosis, and malaria treatment and prevention for 12 African and two Caribbean countries. The money must still be appropriated -- usually the more difficult step in Congress. But authorization is an important start, and the U.S. is expected to use it to lobby for more commitment from other major governments at the G-8 summit (Group of Eight nations), June 1-3 in Evian, France.

You can read the full text of this legislation at the Web site of the Library of Congress, http://thomas.loc.gov. There you can search for the bill number, H.R.1298. The latest version is the current one.

Congresswoman Nancy Pelosi of San Francisco, the House Democratic Leader

and the most informed member of Congress on AIDS, commented briefly on both the strengths and weaknesses of this bill in a speech on May 21 (Extensions of Remarks, May 23):

> * Ms. PELOSI. Mr. Speaker, I rise in strong support of H.R. 1298, The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003. The statistics on AIDS are staggering. According to the United Nations, AIDS has killed over 20 million people since the epidemic began. Every day nearly 14,000 people become infected with HIV, primarily in the developing world and another 8,500 people die.
>
> * It's almost too much to comprehend, but we can respond. And we must. Experts say that a strong global response could prevent nearly two-thirds of the 45 million new infections that are projected by 2020, saving tens of millions of lives.
>
> * This legislation will strengthen our response to the global AIDS pandemic by improving coordination among relevant U.S. agencies, establishing additional accountability mechanisms, and fostering international cooperation through increased contributions to the multilateral Global Fund to Combat HIV/AIDS, Tuberculosis, and Malaria. The increased contribution of up to $1 billion for the Global Fund in FY2004 is accompanied by a 33 percent cap on the U.S. contribution to challenge other donor countries to match our increased commitment.
>
> * The promises made in H.R. 1298, however, must be matched by real resources. Planning and coordination alone will not solve this monumental crisis. Prevention and treatment require money. This is a good first step, now we must appropriate the funds necessary to enact this plan and demonstrate the depth of our commitment to the world.
>
> * H.R. 1298 authorizes $15 billion for our multilateral and bilateral efforts, including $3 billion in FY2004. Unfortunately, the Bush budget provides only $1.6 billion in FY2004, with only $200 million going to the Global Fund. We must do better.
>
> * I also have deep reservations about the provision that gives abstinence programs a third of USAID's prevention funding. This crisis is too severe and our response is too critical to let our efforts be undermined by catering to ideological pressure.
>
> * The fight against AIDS is far from over, and this legislation provides an important opportunity to strengthen our commitment to a future where AIDS is no longer a threat. I urge my colleagues to support the motion to concur.

HIV Nutrition Papers Published

More than 50 medical experts and five U.S. government agencies worked together to produce a series of papers on integrating nutrition with HIV medicine.[1] These papers, addressed mainly to medical professionals, review "general nutritional management, evaluation and intervention for wasting, insulin resistance, fat redistribution, dyslipidemia, lactic acidosis, food safety, and bone abnormalities" (from the introduction). They summarize nutrition doctors should know about when treating HIV disease.

The titles of the articles are:

* Introduction: Integrating Nutrition Therapy into Medical Management of Human Immunodeficiency Virus (introduction by John G. Bartlett)
* General Nutrition Management in Patients Infected with Human Immunodeficiency Virus
* Assessment of Nutritional Status, Body Composition, and Human Immunodeficiency Virus-Associated Morphologic Changes
* Weight Loss and Wasting in Patients Infected with Human Immunodeficiency Virus
* Lipid Abnormalities
* Body Habitus Changes Related to Lipodystrophy

* Insulin and Carbohydrate Dysregulation

* Lactic Acidemia in Infection with Human Immunodeficiency Virus

* Emerging Bone Problems in Patients Infected with Human Immunodeficiency Virus

* Food and Water Safety for Persons Infected with Human Immunodeficiency Virus

References

Integrating nutrition therapy into medical management of human immunodeficiency virus (series of articles). *Clinical Infectious Diseases*. April 1, 2003; vol. 36, supplement 2. The articles are available to the public at:
http://www.journals.uchicago.edu/CID/journal/contents/v36nS2.html

Atazanavir Background Documents Available

Atazanavir (brand name Reyataz™) is a new protease inhibitor developed by Bristol-Myers Squibb that is likely to be approved soon. A May 13, 2003 hearing of the FDA's Antiviral Drugs Advisory Committee decided that the drug has been proven safe and effective, and recommended approval.

Atazanavir, taken once per day, caused much less cholesterol and triglyceride problems than the other protease inhibitors with which it has been compared; however, this improvement did not seem to translate to less lipodystrophy, in the limited data now available. Atazanavir may need to be "boosted" with a small dose of ritonavir in order to be most effective with experienced patients. And some drug interactions will need to be watched carefully to prevent excessive blood levels of atazanavir, which could cause potentially serious changes in heart rhythm.

For much more extensive information on atazanavir see the two documents prepared for the May 13 hearing -- one by the FDA staff, the other by Bristol-Myers Squibb. They are at:
http://www.fda.gov/ohrms/dockets/ac/03/briefing/3950b1.htm.

Remember that this information was current as of May 2003, and will become obsolete as new data become available.

First Clinical Care Options for Hepatitis, June 19-22

For 13 years the Clinical Care Options for HIV Symposium has brought together about 300 front-line HIV doctors for an annual meeting on treating HIV. This year the sponsor, iMedOptions, is beginning a similar meeting on viral hepatitis. The First Annual Clinical Care Options for Hepatitis Symposium, for "experienced, front-line, primary care physicians, gastroenterologists and infectious disease specialists involved in the care of patients with viral hepatitis" will be held June 19-22, 2003, in Laguna Niguel, California.

For more information visit
http://imedoptions.com/hep2003
or phone 800-878-6260.

Surprising Causes of Death in Texas Hospital Study: Safety Net Questions

by John S. James

A study of the changing causes of death of people with HIV at Parkland Memorial Hospital, a major hospital in Dallas, Texas, found that pneumocystis

(also called PCP) is still a major cause of death. And more than half of those with HIV who died of all causes in the study period of 1999-2000 were *not* receiving modern antiretroviral treatment. During this period pneumocystis caused 17% of the deaths, end-stage liver disease 13%, and non-Hodgkin lymphoma 7%. Bacterial pneumonia not considered HIV associated, sepsis, and other non-AIDS-defining infections caused 18% of the deaths, and a group of conditions considered probably immunodeficiency related caused 9%. In a comparison period in 1995, before modern antiretroviral treatment (HAART) was available, more of the deaths were from AIDS-related conditions. But end-stage liver disease caused 10% of the deaths in the earlier period, showing that it is not a new problem.

There was a large decrease in deaths of HIV-infected persons overall -- from 119 deaths in 1995 to 44 in 1999 and 47 in 2000.

Comment

It is often hard to draw conclusions from statistical comparisons of deaths, because the numbers can depend on many factors (like hospital admissions policies) not related to medical care. But the fact that pneumocystis remains the leading cause of death of people with HIV, at one major hospital at least, raises questions about how well the safety net has been working.

There has long been a widespread assumption that almost anyone in the U.S. can get HIV treatment one way or another. We do not know if this is true. Perhaps the belief persists because those who cannot get treatment also cannot get to public attention.

Pneumocystis prophylaxis costs very little, and failure to use it is not due to the expense of the drugs. In this study many patients were not on prophylaxis because their HIV was not diagnosed -- suggesting lack of medical care, due either to lack of access or to the patients' decisions.

Adherence to HAART was a problem, with 39% (18 patients) of those who died in 1999-2000 without HAART listed as not receiving HAART because they were not adherent -- and 26% not receiving HAART because they were diagnosed shortly before death. We know from general experience that many adherence problems result from difficulty in obtaining a continuing supply of medicine -- including inflexible reimbursement rules that may make it difficult to replace lost medicines, or that leave too short a window to refill a prescription when patients have many other balls in the air. Physicians may not know whether non-adherence is due to economic obstacles.

Parkland Memorial Hospital is well regarded and accepts patients on an ability-to-pay basis. But Texas has long been seen as one of the worst states for access to HIV care (though improving now, due to grassroots organizing).

Cause-of-death studies can give us unique information about how well the medical safety net is working or not working. This one suggests that access

to care may be less than generally believed, even before the funding crisis that is developing now.

References

Jain MK, Skiest DJ, Cloud JW, Jain CL, Burns D, and Berggren RE. Changes in mortality related to human immunodeficiency virus infection: Comparative analysis of inpatient deaths in 1995 and in 1999-2000. *Clinical Infectious Diseases.* April 15, 2003; number 36, pages 1030-1038.

Glaxo Drug Discovery and Development Research Grants (Including Microbicides); Deadline July 31

GlaxoSmithKline will award research grants from $25,000 to $150,000 ($500,000 total) "for innovative HIV/AIDS drug research in recognition of the need to produce new alternatives and hope in the fight against the HIV/AIDS pandemic." These grants "are intended to further the development of inventive treatments for HIV/AIDS, including: therapies aimed at treating infection; prophylactic vaccines; or microbicides designed to prevent transmission of the virus." Applications will be judged by a panel of outside experts; recipients will be announced at the ICAAC conference in September 2003; and the grants will be paid by November 1. There is no obligation to license resulting technologies to Glaxo.

For more information and application forms, visit http://www.dddresearchgrant.com or call 888-527-6935.

Africa: Problems Getting Antiretrovirals for Trials

Researchers are having continuing difficulties getting the drugs for trials of antiretrovirals in developing countries. Writer Jon Cohen outlined the problem in an article in the current *Science* magazine (May 26, 2003).

The U.S. National Institutes of Health conducts some drug trials in developing countries -- but will not pay for the drugs, which are normally donated by the manufacturer for U.S. trials leading to drug approval. But generally the drugs used in these developing-country trials have already been approved in the U.S., and companies have little incentive to donate them for these trials, which usually focus on operations research on how to best deliver treatment in developing countries. And for ethical reasons the U.S. insists that patients be offered continued treatment after the trial -- a disincentive for the manufacturers or anyone else to provide drugs. For various reasons the researchers often cannot or do not want to use lower-cost generic versions of the

drugs.

Cohen quotes well-known AIDS researcher Bruce Walker, whose study in South Africa has been delayed for a year:

"Right now, there are plenty of groups like ours that are ready to treat people, and we can't get drugs... The absurdity of the situation is that 95% of HIV infections exist in countries where you have minimal experience giving the drugs...

"We're letting a lot of people die because we're saying [you must treat] forever. We have plenty of people who were dying who are now alive because they're on therapy. People would rather be alive and faced with having to figure out what they're going to do in three years than be dead."

Comment

These problems would never be tolerated if it were killing people in the U.S. and Europe instead of mostly in Africa.

In recent years a few activists have successfully demanded that the ethical standards that evolved in developed countries be applied without flexibility to research everywhere -- a policy some Africans called ethical imperialism. Now the consequences -- sometimes no research at all -- are here.

The consensus that researchers must offer continued treatment after a trial evolved in the context of testing experimental drugs -- on volunteers who took the risk of unknown side effects or of a drug that did not work, and had no control over whether they received the experimental drug or were randomly assigned to something else. The company hoping to benefit commercially from the research was expected to offer continued treatment to these volunteers either until the drug was approved (so patients could buy it if it helped them), or dropped from development (usually because the drug did not work or was unsafe). To morph this ethical standard onto operations research in developing countries -- with drugs already known to work and approved for routine use, with no pharmaceutical company standing to benefit, with no time limit on how long the researchers must plan to finance the drugs after the trial, and with much lower cost generics becoming available for continued treatment but not to the researchers -- is an absurdity never imagined when the consensus for continuing access to treatment developed.

The world must not stand by and let critically important research be halted because companies and governments evade responsibility, or because of the unthinking misuse of well-intentioned ideas.

Funding Alert: Wake Up and Support WORLD

by John S. James

People with HIV in the U.S. face a growing emergency as Federal policy starves human services during an economic downturn, and essential medical care becomes less available to most people who need it. Since almost no one can afford antiretroviral treatment entirely out of pocket, and private insurance has found ways of avoiding or dumping patients who become seriously ill, public programs have become a last resort. Now these programs are under the worst financial threat ever. People are already being denied treatment for AIDS and other diseases who until recently could have obtained it, and the crisis will get worse. Communities must think carefully about what they can do to protect themselves. Some facts are clear:

* Private charity can never pay for

most peoples' medications at $10,000 or more per person per year, in addition to other medical care and expenses of patients unable to work full time.

* But private funding is crucial for medical information to help people take care of themselves, and for advocacy toward workable policies so that people can receive the medical care they need. The goal is not necessarily to get government to pay, but to bring public and private institutions together for responsible solutions to the growing lack of healthcare access in this country. Government funds usually cannot be used for advocacy, so without private support it will not be done.

* Pharmaceutical company funding of community organizations has made possible important work. But it would be a serious mistake to become entirely dependent on an industry that shares some community goals (such as getting public programs to pay for medicines), but must focus first and last on sales and profits.

* In the U.S., individuals give much more money to charitable organizations (mostly to religious groups) than foundations and corporations put together.

A major problem in fundraising is that most potential donors are too busy to be personally involved in the work being funded, and therefore are not very familiar with what is really going on. So organizations reach donors emotionally, or by providing networking opportunities for them. This is necessary and useful. But it can reward organizations more for good fundraising than for good service work.

We need activism that can bridge the communication gap between those doing important advocacy or service and those who can fund it. These activists need to know both groups and be credible in both, to be a kind of ambassador between them. They may need special talent, background, or training.

So far only a handful have been doing this work, as the AIDS community has not made it a priority. The community must recognize the importance of this role and provide encouragement, models, training, and other support. Then organizations doing important work can survive hard times.

If we do not have significant funding independent of government and corporations, we will lose control of our future to forces that have always been hostile to people with AIDS.

Example: WORLD

WORLD (Women Organized to Respond to Life-Threatening Diseases), based in Oakland, California but working nationally and beyond, is one of many advocacy and service organizations that do good work and need community support for it.

WORLD, active for 12 years, has published 143 issues of its monthly newsletter "by, for, and about HIV+ women and their loved ones," currently reaching 12,000 people in 87 countries. It conducts two retreats each year for HIV-positive women, and also HIV University, a treatment school for women.

This year donations are down, and the newsletter had to be suspended until money can be found for printing and postage. The AIDS Walk usually funds the two retreats, but this year there was only enough money for one, and the other had to be cancelled. And funding has not yet been found for this year's HIV University.